

SUPPORT FOR THE AMENDMENTS

Claim 1 has been canceled.

Claims 2-8, 10, and 11 have been amended.

Claims 12-21 have been added.

Support for the amendment of Claims 2-8, 10, and 11 is provided by the corresponding claims as originally filed and by the specification at, for example, paragraphs [[0009]-[0028] on pages 2-7. Support for new Claims 12-21 is provided by, for example, paragraphs [0029]-[0036] on pages 7-9 and the Examples.

The specification has been amended to correct an error introduced in the original PCT application when converting from the Japanese priority application (JP 2003-197096). Specifically, Example 1 was duplicated as Example 2; Example 2 was inserted as Example 3; and Example 3 was inadvertently omitted. To correct this error, Applicants have amended the specification herein by deleting the text at page 10, ranging from lines 6 to 20, which results in the deletion of duplicated Example 1. With this amendment original Example 2 is now properly designated as such, rather than as Example 3. Applicants have also inserted the text for Example 3 at page 10, between lines 32 and 33. Support for these amendments are found in the Examples (see pages 20-22) of the certified English translation of JP 2003-197096 **submitted herewith**. Applicants submit that this error and its correction would be readily apparent to the skilled artisan, which would be further manifest in a comparison between the reported results in the present specification and those appearing in certified English translation of JP 2003-197096.

No new matter has been added by the present amendments.

REMARKS

Claims 2-21 are pending in the present application.

The rejections of: (a) Claims 1-2 and 9 under 35 U.S.C. §102(b) and (b) Claim 3 under 35 U.S.C. §103(a), each over Winston et al (WO 98/13012) is obviated in part by amendment and traversed in part.

At the outset, Applicants submit that Claim 1 has been canceled. Therefore the rejection over this claim is now moot. Further, Claims 2 and 3 have been amended to depend directly from Claim 9. As such, for at least the reasons why Claim 9 is patentable over Winston et al, so too is Claims 2 and 3.

With respect to Claim 9, Applicants submit that Winston et al fail to disclose or suggest alternately applying a first composition (A) and a second composition (B) to a tooth where the first composition (A) contains a fluoride ion-supplying compound and an inorganic phosphoric acid or a salt thereof; and the second composition (B) contains a calcium salt of organic acid, wherein an organic acid constituting the calcium salt of organic acid has a pKa value ranging from 3 to 11, or at least one pKa value ranging from 3 to 11 when the organic acid has plural pKa values. Accordingly, Applicants submit that the claimed invention is not anticipated by or obvious in view of Winston et al.

Winston et al disclose one-part or two-part products for remineralizing or mineralizing teeth (see Abstract). However, throughout the specification, Winston et al disclose that “when the product... is ready to be used, the cationic and anionic components are mixed together with water and/or saliva to form the mixed aqueous composition... The anionic and cationic components are mixed only when the components are introduced into the oral cavity or immediately before their introduction into the oral cavity” (see page 23, line

29 to page 24, line 6). Further, at page 36, lines 11-29, Winston et al specifically disclose “When using the two-part aqueous products of this invention, the time period between the mixing of the first and second parts and the application of the resulting mixed aqueous composition to the teeth should not exceed 1 minute.... An important feature of the present invention lies in the mixing of the anionic and cationic components and the quick and timely application of the resulting mixed composition to the tooth...”

In view of the foregoing and the remainder of the disclosure by Winston et al, including the Examples, it is clear that the two-part system disclosed therein is either mixed simultaneously (at best in the oral cavity as opposed to on the tooth surface) or pre-mixed before application to the oral cavity or teeth. In contrast, the claimed invention requires the alternate application of composition (A) and composition (B). The meaning of “alternate application” is clear from the disclosure of the present application and means that either composition (A) or composition (B) is applied to the teeth followed after a certain time interval the application of the other composition (see, for example, paragraphs [0011], [0019], and [0032]-[0034], and the Examples). Winston et al does not disclose or suggest the alternate application as claimed.

The foregoing distinction is important for two reasons. First, the fact that Winston et al does not disclose or suggest the alternate application as claimed means that this reference cannot anticipate the claimed invention. Second, Applicants submit that the claimed method provides a substantial unexpected advantage with respect to flurine uptake as compared to either simultaneously applying (A) and (B) or pre-mixing (A) and (B) prior to application, each of which is more representative of the disclosure of Winston et al.

Even, *arguendo*, the Examiner’s alleged application of Winston et al were to provide the basis for a *prima facie* case of obviousness, it is well-established that the *prima facie* case

may be rebutted by the evidentiary showing of unexpectedly superior results. To this end, the Examiner's attention is directed to the Declaration under 37 C.F.R. §1.132 ("the 132 Declaration") **submitted herewith**. In the 132 Declaration, Applicants show the following comparison of the results obtained as a measure of fluorine uptake ( $\mu\text{g}/\text{cm}^2$ ) for the claimed method and two methods that are representative of the disclosure of Winston et al:

	Alternately applying (A) and (B) <sup>i</sup>		Simultaneously applying (A) and (B) <sup>ii</sup>		Pre-mixing (A) and (B) <sup>iii</sup>	
	1 min.	3 min.	1 min.	3 min.	1 min.	3 min.
Example 1	5.2	13.5	0.3	0.4	0.1	0.2
Example 2	5.8	15.8	0.6	0.6	0.2	0.2
Example 3	4.9	11.5	0.8	0.9	0.3	0.4
Example 4	0.6	5.2	0.2	0.2	0.1	0.1
Example 5	0.3	3.8	0.1	0.1	0.1	0.1

i) Alternately applying (A) and (B): alternately at 10 second intervals

ii) Simultaneously applying (A) and (B): mixed at teeth

iii) Pre-mixing (A) and (B): pre-mixed for 10 seconds prior to application to teeth

These results clearly evidence the unexpected superiority of the claimed method with respect to fluorine uptake is demonstrated as compared to method representing the disclosure of Winston et al.

In view of the foregoing, Applicants respectfully request that these grounds of rejection be withdrawn.

The rejections of: (a) Claims 8 and 10 under 35 U.S.C. §102(b) over Wiesel (US 6,287,120) and (b) Claim 11 under 35 U.S.C. §103(a) over Wiesel in view of Winston et al is respectfully traversed.

Winston et al and its deficiencies are discussed above. Wiesel discloses methods and apparatus for treating a person's teeth, which are specifically carrier coated or impregnated with a paste, gel, or solution, which contains medicaments. As cited by the Examiner, at column 3, line 66 through at column 4, line 4, Wiesel discloses that "a non-woven, porous material is used as a carrier. The carrier impregnated with medicaments is applied to a person's teeth. Additional solution can be applied to the porous material while it remains on the patient's teeth." At column 8, lines 28 to 37, the Examiner notes that Wiesel discloses that "the carrier 110 may be used for repairing or remineralizing tooth enamel.... , for example, ENAMELON."

Following the citation of the foregoing sections, the Examiner makes the following two allegations:

- 1) "It is understood that the invention of Winston discussed above is Enamelon." (see page 4, lines 7-8 of the Office Action mailed February 15, 2008) And,
- 2) "The reference anticipates the instant claims insofar as they teach a product for dental treatment comprising a composition (A) containing a fluoride ion-supplying compound and an inorganic phosphoric acid salt; and composition (B) containing a calcium salt of malonic acid wherein (A) and/or (B) is supported on a carrier selected from the group consisting of paper, cloth, nonwoven fabric, absorbent cotton, sponge and porous film, and wherein the compositions (A) and (B) are discrete from each other so that the two compositions can be alternately used and then come to be mixed with each other at each tooth region when applied thereto." (see page 4, lines 11-18 of the Office Action mailed February 15, 2008)

First, with respect to allegation (1), the Examiner apparently relies upon "ENAMELON" to support the notion that components (A) and (B) are disclosed. However, Applicants submit that the Examiner offers no support for such an allegation. When an

Examiner maintains that there is an implicit teaching or suggestion in the prior art, “the Examiner should indicate where (page and line or figure) such a teaching or suggestion appears in the prior art.” *Ex parte Jones*, 62 USPQ2d 1206, 1208 (Bd. Pat. App. & Inter. 2001). Therefore, the Office has not met the burden necessary to establish anticipation or obviousness of the claimed invention.

Further, even if the Examiner could somehow show that ENAMELON were the product disclosed by Winston et al, there is absolutely no disclosure or suggestion by Wiesel that compositions (A) and (B) are discrete from each other so that the two compositions can be alternately used and then come to be mixed with each other at each tooth region when applied thereto. Moreover, even looking at the combined disclosures of Wiesel and Winston et al, there is no disclosure or suggestion that either (A) or (B) should be supported on a carrier selected from the group consisting of paper, cloth, nonwoven fabric, absorbent cotton, sponge and porous film, much less that (A) and (B) should be alternately applied. Notably, as discussed above and evidenced by the 132 Declaration, the unexpected results demonstrated for the claimed invention would rebut even a *prima facie* case of obviousness.

Indeed, with respect to the alternate application of compositions (A) and (B), Applicants note that the section referenced by the Examiner at column 3, lines 65-67 and column 4, lines 1-5 of Wiesel does not support the Examiner’s apparent interpretation based on the allegation that Wiesel “teaches that the carrier is a non-woven, porous material which is first dipped in one solution and that additional solution may be applied to the porous material while it remains on the patient’s teeth”

It appears that the Examiner is interpreting this section as disclosing that the alternate application of (A) and (B). However, again, it is submitted that there is no disclosure by Wiesel of either (A) or (B). Nonetheless, Applicants submit that even if there were, this

citation by the Examiner merely directs the artisan to add more of the *same* solution to the non-woven porous material rather than a different solution. Thus, Claim 8 cannot be anticipated.

Further, the claimed method is not even anticipated or obvious as even if it were taken as a suggestion to apply a second solution, Applicants submit that the application is not to the tooth as presently claimed, but rather would be application to the carrier. It is also submitted that Wiesel discloses methods for treating teeth using the carrier 110, but no methods for treating teeth replacing the carrier 110 by another one. In addition, Wiesel does not disclose not only the inventions where one of compositions is a mouthwash and other composition is a dentifrice (see new Claims 20-21).

With respect to allegation (2), Applicants submit that this mere restatement of the claimed invention is unsupported by the facts of this case and is inaccurate.

As for the additional citation of Winston et al to support the Examiner's alleged rejection of Claim 11 as being obvious, Applicants direct the Examiner's attention to the foregoing arguments and the 132 Declaration evidencing the unexpected advantages flowing from the claimed invention. For these reasons, Applicants further submit that the claimed method is not obvious in view of the combined disclosures of Wiesel and Winston et al.

In view of the foregoing, Applicants respectfully request that these grounds of rejection be withdrawn.

The objection of Claims 1-11 due to the recitation of the phrase "given below" is obviated by the deletion of this phrase. Applicants request withdrawal of this ground of rejection.

The objection to Claims 4-7 under 37 C.F.R. §1.75(c) as containing improper multiple dependencies is obviated by amendment. Applicants request withdrawal of this ground of rejection.

The objection to Claims 1-11 due to the lines being crowded too closely together making reading difficult is obviated by the submission of the amended claims appearing on pages 2-6 of this response. Withdrawal of this ground of objection is requested.

Applicants submit that the present application is now in condition for allowance. Early notification of such action is earnestly solicited.

Respectfully submitted,

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